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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,284	04/21/2005	Eric Fredericus Bernardus Josephus Mar Thunnissen	13634PCTUS	1854
23719	7590	05/28/2008		
KALOW & SPRINGUT LLP 488 MADISON AVENUE 19TH FLOOR NEW YORK, NY 10022			EXAMINER WOOLWINE, SAMUEL C	
			ART UNIT 1637	PAPER NUMBER PAPER
			MAIL DATE 05/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,284	<b>Applicant(s)</b> THUNNISSEN ET AL.
	<b>Examiner</b> SAMUEL WOOLWINE	<b>Art Unit</b> 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on 17 September 2007.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4 and 10-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-4 and 10-17 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-146/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status***

Applicant's amendment filed 09/17/2007 is acknowledged. Previously, claims 1-9 were examined and rejected over the prior art of Manos et al (U.S. Pat. No. 5,182,377) under 35 U.S.C. 102(b), and Manos et al in view of Fodor (U.S. Pat. No. 5,925,525). Applicant explicitly agreed with the rejections (page 5 of the reply filed 09/17/2007).

These rejections as well as the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in view of Applicant's amendment. In particular, Applicant has amended the claims to recite specific primer and probe sequences (SEQ ID NOs), which are not taught by either Manos or Fodor. However, the prior art of Manos, which Applicant agreed anticipated or, in combination with Fodor, rendered obvious the previous claims serves as a basis for a finding of lack of unity of invention as regards the amended claims.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The number of independent and distinct inventions encompassed by the pending claims is too numerous to easily calculate. In short, independent claims 1 and 4 require

"at least two" oligonucleotides (primers) selected from the group consisting of SEQ ID NOs 1 to 23. Independent claim 14 requires "at least two" immobilized capture probes selected from the group consisting of SEQ ID NOs 24-59. Hence, Applicant's claims encompass multiple patentably distinct combinations of primers and probes. For instance, the number of possible combinations of just two of SEQ ID NOs 1-23 would be  $23 \times 22 = 506$ . The number of possible combinations of three of these is  $23 \times 22 \times 21 = 10,626$ , and so on. When each combination of two or more primers is used with each possible combination of two or more probes, one can see that an astronomical number results. The only thing all of the possible combinations of primers and probes share is that they can be used to amplify and detect a portion of the HPV E1 gene. However, these combinations do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Manos et al (U.S. Pat. No. 5,182,377) teaches primers and probes for amplifying and detecting the E1 gene of HPV (see Office action dated 03/22/2007 and in particular see Manos at column 14, lines 38-44, Table 9, column 15, lines 8-30).

Applicant is required in reply to this Office action to elect one combination of primers and one combination of probes (i.e SEQ ID NOs) to which the claims will be restricted. For example Applicant may elect the combination of SEQ ID NOs 1, 6, 10 and 15 (for primers) and 23-28 (for probes). Applicant may elect for the combination as many primers and probes from the recited SEQ ID NOs as desired with the understanding that all claims will be limited to that combination of SEQ ID NOs, and no

additional SEQ ID NO will be recited in the claims (as in, "the method of claim 1 further comprising the primers SEQ ID NOs X, Y, Z"). Hence, the more sequences chosen to be part of the elected combination, the narrower the scope of the claims and *vice versa*.

Due to the complex nature of the requirement being imposed, a written requirement for restriction is being sent in lieu of a telephone call (MPEP 812.01).

Applicant is advised that the reply to this requirement to be complete must include an election of the combination of SEQ ID NOs to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

scw

/Young J Kim/  
Primary Examiner, Art Unit 1637